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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/443,842	11/19/1999	MEHMET TONER	22727-41	7776

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EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/08/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/443,842

Applicant(s)

Toner et al.

Examiner

Vera Afremova

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 14, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-102 is/are pending in the application.
- 4a) Of the above, claim(s) 37-72 and 90-102 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 73-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Election/Restriction

Applicant's election with traverse of The Group IV (claims 73-89), drawn to a method for preserving nucleated cells having lipid membranes, in Paper No. 8 is acknowledged. The traversal is on the ground(s) that some of the groups are classified in the same class and subclass, the "elected" subject matter would necessarily involve an overlapping search of the entire subject matter presently claimed and particularly for groups III, IV and V.

However this is not found persuasive because the methods are of a different scope such as subjects under treatment for the methods of the Groups III and V are "mammalian cells" as claimed but not "nucleated cells" as claimed for the Group IV method. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exists. Further, it is doubted that applicants would readily accept the rejection of the process of the three groups as argued over a reference cited during prosecution of parent application, for example: US 5,242,792, which is related to preservation of red blood cells which are mammalian cells but not nucleated cells, the latter being required for the method of the presently elected Group IV. Clearly different searches and issues are involved with each group.

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For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL. Claims 37-72 and 90-102 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions.

Claims 1-36 were canceled by applicants in the Paper No. 5 filed 7/05/2001.

Claims 73-89 are under examination in the instant office action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37CFR 3.73(b).

Claims 73-89 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,127,177. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to similar methods for preserving and storing nucleated cells by using both steps of reversibly porating nucleated cells and loading the porated nucleated cells with a specific

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amount of a bio-preserving agent. Some claims of the present invention are broader with regard to the concept of “reversibly porating” the nucleated cells as claimed which is not limited to a particular porating protocol or agent of US 6,127,177. Some of the claims of the present invention encompass the use of the same porating agent such as “membrane toxin” which is required for the whole claimed invention of US 6,127,177. However, some of the claims of the present invention are broader and they are not limited to preserving and storing of mammalian cells as the method of US 6,127,177. Accordingly, the inventions as claimed are co-extensive. And the claimed methods are obvious variants.

Claim Rejections - 35 USC § 112

Scope

Claims 73-75 and 80-89 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method for preserving nucleated cells by “reversibly porating” the nucleated cells by a specific protocol encompassing the use of a “membrane toxin”, does not reasonably provide enablement for the method for preserving nucleated cells by a generic or unspecified protocol of reversible poration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

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Nature of the invention is directed to the use of a membrane toxin in the method for bio-preservation of a cellular material comprising a reversible poration of the cellular material which is loaded with bio-preservation agent and stored.

Breadth of the claims is directed to a method for preserving nucleated cells comprising a step of reversibly porating the cellular material which is loaded with bio-preservation agent and stored.

Amount of guidance and working examples are limited to the use of a "membrane toxin" in the method for bio-preservation of cellular material wherein a particular membrane toxin is a *Staphylococcus aureus* alpha toxin or H5 alpha-toxin. The concept of "reversibly porating" membrane of the cellular material prior to loading the bio-preserving agents and further storing the cellular material as disclosed in the as-filed specification does not provide teaching or suggestion drawn to other than either generic "membrane toxin" or particular *Staphylococcus aureus* alpha toxin. The use of a membrane toxin is the only example in the protocol intended for a step of "reversibly porating" membrane of the cellular material in the method for bio-preservation of cellular material.

The prior art does not appear to teach other examples or embodiments of "reversibly" porating the cellular material intended for loading with biopreservation agent and storing. Therefore, neither specification nor the prior art can be said to support the enablement of the claims over their breath. Thus, it is considered that undue experimentation would be required to practice the invention as claimed due to the amount of experimentation necessary because of the

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limited amount of guidance and limited number of working examples in the specification with regard to a generic concept of reversible poration.

As set forth in *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA) 1970: [Section 112] requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.

In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of the enablement varies inversely with the degree of unpredictability of the factors involved. *Ex parte Humphreys*, 24 USPQ2d, 1260.

Indefinite

Claims 73-89 are rejected under 35 U.S.C. 112, *second paragraph*, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 73 is indefinite because it appears to lack an antecedent basis for mammalian cells in step d) as claimed.

Claim 73 is also indefinite because it appears to lack an antecedent basis for “the cellular material” in step b) wherein it is not particularly clear whether the material is loaded is the same material which is known as control for determination of a “sufficient” concentration.

In addition, the phrase “cryopreserving” in step c) of claim 73 contains a typing error.

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Claim 74 is indefinite because it appears to lack a proper antecedent basis for the phrase "cellular material" as claimed.

Claims 83-85 and 87 are indefinite because they appear to lack a proper antecedent basis for the mammalian cells.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

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May 7, 2002.

V.A.


SANDRA E. SAUCIER
PRIMARY EXAMINER